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**TRANSMITTAL  
FORM**

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Total Number of Pages in This Submission

27

Application Number

09/830,300

Filing Date

July 5, 2001

First Named Inventor

Achim Berthold

Art Unit

1616

Examiner Name

Sharmilla S. Gollamudi

Attorney Docket Number

R00282US.RCE2 (#90568)

**ENCLOSURES (Check all that apply)**

Fee Transmittal Form



Fee Attached



Amendment/Reply



After Final



Affidavits/declaration(s)



Extension of Time Request



Express Abandonment Request



Information Disclosure Statement



Certified Copy of Priority Document(s)

Reply to Missing Parts/  
Incomplete ApplicationReply to Missing Parts  
under 37 CFR 1.52 or 1.53

Drawing(s)



Licensing-related Papers



Petition

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Appeal Communication to Board  
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(Appeal Notice, Brief, Reply Brief)

Proprietary Information



Status Letter

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**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm Name

D. Peter Hochberg Co., L.P.A.

Signature

Printed name

D. Peter Hochberg

Date

September 27, 2006

Reg. No.

24,603

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Sean Mellino

Date

09/27/2006

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Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

**FEE TRANSMITTAL**  
**For FY 2006**☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$) 0.00**Complete if Known**

Application Number	09/830,300
Filing Date	July 5, 2001
First Named Inventor	Achim Berthold
Examiner Name	Sharmilla S. Gollamudi
Art Unit	1616
Attorney Docket No.	RO0282US.RCE2 (#90568)

**METHOD OF PAYMENT** (check all that apply)

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**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180
<b>Total Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>
- 20 or HP =	x	=
HP = highest number of total claims paid for, if greater than 20.		
<b>Indep. Claims</b>	<b>Extra Claims</b>	<b>Fee (\$)</b>
- 3 or HP =	x	=
HP = highest number of independent claims paid for, if greater than 3.		

**Multiple Dependent Claims**

Fee (\$) Fee Paid (\$)

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

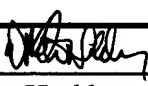
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**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

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Signature		Registration No. (Attorney/Agent)	24,603	Telephone	216-771-3800
Name (Print/Type)	D. Peter Hochberg		Date	September 27, 2006	

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Sept. 27, 2006  
Date

Sean F. Mellino  
Sean F. Mellino

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant : Achim Berthold

Serial No. : 09/830,300 / Conf. No. 8251

Filing Date : July 5, 2001

Examiner / Group Art Unit : Sharmila S. Gollamudi / 1616

Title : Therapeutic System Containing an Active  
Substance for the Application on the Skin which  
Contains at least Two Polymerous Layers

Attorney File : RO0282US.RCE2 (#90568)

Technology Center : 1600

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**REPLY BRIEF**

Dear Sir:

This reply brief is in response to the Examiner's Answer which was mailed on  
July 27, 2006 in response to the Applicant's Appeal Brief filed on April 20, 2006.

**STATUS OF CLAIMS:**

Claims 1-32 are canceled. Claims 33-43 are pending in the application. The rejection of claims 33-43 is being appealed.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL:

The following issues are present in the present appeal:

1. Was the rejection of claims 33-43 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement proper?
2. Was the rejection of claims 33-43 as being unpatentable over U.S. Patent No. 5,151,271 (Otsuka *et al.*) by itself or in view of U.S. Patent No. 6,063,838 (Patnode, *et al.*) under 35 U.S.C. §103(a) proper?
3. Was the rejection of claims 33-43 as being unpatentable over U.S. Patent No. 5,151,271 (Otsuka *et al.*) by itself or in view of U.S. Patent No. 5,023,084 (Chien, *et al.*) under 35 U.S.C. §103(a) proper?

ARGUMENT:

The rejection of claims 33-43 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, the rejection of claims 33-43 as being unpatentable over U.S. Patent No. 5,151,271 (Otsuka *et al.*) by itself or in view of U.S. Patent No. 6,063,838 (Patnode, *et al.*) under 35 U.S.C. §103(a) and the rejection of claims 33-43 as being unpatentable over U.S. Patent No. 5,151,271 (Otsuka *et al.*) by itself or in view of U.S. Patent No. 5,023,084 (Chien, *et al.*) under 35 U.S.C. §103(a) are improper and should be reversed.

The Examiner first states in the Final Office action dated October 19, 2005, on page 2, that the instant specification has support for three polymer-containing layers, as evidenced by Figure 1 in the specification. However, in the "Response to Argument" of the Examiner's Answer, the Examiner maintains the position that the specification and Figure 1 only provide support for a system that has two layers with different glass transition temperatures rather than three, referencing Figure 1 and page 10 as support for this position. Consequently, the Examiner argues in the Final Office action and in the "Grounds of Rejection" in the Examiner's Answer that the recitation "the glass temperature Tg1 of the polymer of the first layer and the glass transition temperature Tg3 of the polymer of said third layer are identical *or different* (emphasis provided)" does not have any support in the specification since there is only support for the first layer and the third layer having identical glass temperatures. Therefore, the Examiner considers the limitation "different" to be new subject matter.

The Examiner next states in the Final Office action and Examiner's Answer commencing on page 3 therein that claims 33-43 are rejected as being unpatentable over

Otsuka, et al. by itself or in view of Patnode, et al. The Examiner argues that Otsuka, et al. teach a pressure sensitive adhering composite medicinal preparation to provide drug supply to the skin and that the composite comprises **at least** (emphasis provided) two layers, namely, **at least one** (emphasis provided) pressure-adhering macromolecular substance layer and polymer layer adjacent to the macromolecular substance layer. The Examiner goes on (Examiner's Answer, pages 4 and 17) to state that the polymer layer contains a polymer or copolymer that has a glass transition temperature (T<sub>g</sub>) of not lower than -50 degrees Celsius, preferably -45 to +45 degrees Celsius. The Examiner ultimately argues that Otsuka, et al. teach every limitation of claims 33-43, except for the third layer.

In this regard, the Examiner argues that it would have been obvious to refer to Otsuka, et al. and incorporate a third polymer-containing layer, with motivation to do so lying in the teaching of Otsuka, et al. that the composite should contain *at least* (emphasis provided) two layers and in particular *at least one* (emphasis provided) macromolecular layer (Examiner's Answer, page 4). The Examiner argues that if a skilled artisan followed the suggestion provided by Otsuka, et al. and utilized two macromolecular layers, that skilled artisan would arrive at the instant invention wherein the invention would have a macromolecular layer corresponding to T<sub>g1</sub>, a polymer layer corresponding to T<sub>g2</sub> and the second macromolecular layer corresponding to T<sub>g3</sub> (Examiner's Answer, page 6). Still further, the Examiner states the polymer layer would be sandwiched in between the two macromolecular layers as instantly claimed since Otsuka, et al. teach the macromolecular layer must be in contact and adjacent to the polymer layer (Final Office action, page 6).

The Examiner relies on Patnode, et al. to teach the deficiencies of Otsuka, et al. (Examiner's Answer, page 6). The Examiner believes that it would have been obvious to one of ordinary skill in the art to combine the teachings of Otsuka, et al. and Patnode, et al. in order to utilize a third pressure sensitive layer (Final Office action, pages 6-7).

The Examiner proceeds to repeat the analysis of Otsuka, et al. (Examiner's Answer, pages 6-9), but relies on Chien, et al. to also support the missing teachings of Otsuka, et al. It is argued by the Examiner that Chien, et al. teach a multilaminate device containing a first adhesive layer with a first drug which correlates to Otsuka, et al.'s macromolecular layer, a separating layer which correlates to Otsuka, et al.'s polymer layer and another adhesive layer containing a second drug, which correlates to Otsuka, et al.'s suggested second macromolecular layer. Therefore, the Examiner concludes that if one desired to utilize different drugs for combination therapy as known in the prior art, one would have been motivated to utilize another pressure sensitive adhesive macromolecular layer, which has a lower glass temperature than the polymer layer (Examiner's Answer, page 9).

**Rejection of claims 33-43 under 35 U.S.C. 112, first paragraph**

The applicant again respectfully traverses this rejection on the basis that the term "or different" is new matter and submits that the original disclosure provides support for either of two instances, as noted in the Appeal Brief: (1) where the system has three layers and the polymer of the first and third layers have the same Tg while the polymer of the second layer has a second Tg; and (2) where the system has three layers and all three layers have a polymer having a different Tg.



The Examiner maintains the position in the “Answer” (page 3, part (A)) that the specification and Figure 1 only provide support for a system that has two layers with different glass transition temperatures ( $T_g$ ) and not three, and thus concludes that the recitation “the glass temperature  $T_{g1}$  of the polymer of the first layer and the glass transition temperature of the  $T_{g3}$  of the polymer of said third layer are identical *or different*” is not supported since there is only support for the first layer and the third layer having identical glass temperatures. In addition, the Examiner maintains the position that there is no support for a device wherein the  $T_{g3}$  is not only different from  $T_{g1}$  but is also lower than  $T_{g2}$ .

At pages 9-12 of the Answer (part (10)(A)), the Examiner provides a direct rebuttal to the applicant’s arguments against the rejection under 35 USC 112, first paragraph. In particular, the Examiner notes that the Appellant’s arguments are not persuasive because, although the specification, on pages 9 and 10, discloses that the layers differ in their glass temperature and there is support for two layers that have two different glass layers, there is no support for a layer  $T_{g3}$  wherein that layer has a different glass transition temperature from the other  $T_{g1}$  and  $T_{g2}$ . The Examiner also notes in the Answer that there is support for more than one layer, by way of the phrase “at least two” and Figure 1; however, the Examiner argues that this is not enough to provide support for the third layer having a different  $T_g$  temperature from the first layer.

The Examiner also provides the alternative position where it is assumed that there is support for all three layers having a different glass transition temperature. In this case, the Examiner argues that there would still not be support where the third layer not only has a glass transition temperature ( $T_{g3}$ ) that is different from the first layer’s glass

transition temperature (Tg1), but also has a lower glass transition temperature than the second layer (Tg2). The Examiner further argues that the specification does not disclose that if Tg3 is different it must have a lower temperature than Tg2. Additionally, it is argued by the Examiner in the Answer (page 11) that the only (emphasis provided) brief disclosure of the glass temperatures in relation to the other layers is on one line on page 10, line 18, wherein Appellant states that Tg2 is greater than Tg1. Thus, the Examiner concludes that the only disclosure is a device that has three layers wherein the first layer and the third layer have the same glass temperature and the first and third layer have a lower Tg than the second layer.

As noted above, the Examiner agrees that there is support for the present configuration having “at least two layers.” This is supported by Figure 1 which shows three layers and the original specification at page 8, lines 21-24 where it states “an active substance-containing therapeutic system for application on the skin comprising at least two polymer-containing layers...” This of course can mean three layers, four layers, five layers, etc. The very next sentence (page 6, lines 1-2) states “The various layers differ in their glass transition temperature (Tg).” This same language is provided at page 10, lines 1-5 wherein it states “[A] process ... laminating at least two polymer-containing layers upon one another, with the layers containing polymers which differ in their glass transition temperature.” Original claims 1 and 5 also included this same language. It is respectfully submitted that this language clearly and unequivocally provides support that the “at least two layers,” i.e., three layers, four layers, five layers, etc., can all have a different glass transition temperature (Tg) from each other. The Appellant states that the

in their glass transition temperature, as was the Appellant's intention when this application was prepared.

In other words, Tg1 originally referred to the glass transition temperature of both the first layer and the third layer, such as is shown in Figure 1. This would imply that Tg1 of the first layer and Tg1 of the third layer could be the same. As set forth in the specification (as noted above), the glass transition temperatures of the layers differed. Applying this recitation of the specification to Figure 1, it would be clear to one skilled in the art that Tg1 of the first layer and Tg1 of the third layer could also be different in an alternative embodiment.

The Appellant respectfully wishes to submit the reason for amending the claim language to read "Tg3" with reference to the third layer, rather than having Tg1 refer to both the first layer and the third layer. In response to the Office action dated December 20, 2002, claim 15 was amended to clarify the limitation "the polymers in the respective layers differ in glass transition temperatures." This particular phrase had been deleted from claim 15 and clarified by reciting "a first layer comprises ... (Tg1), a second layer comprises...(Tg2), and a third layer comprises ...(Tg1), said second layer being located between said first layer and said third layer; and wherein Tg2 is greater than Tg1, and the glass transition temperature Tg1 of the ...first layer and the glass transition temperature Tg1 ... of said third layer are identical or different." This language was in compliance with the embodiment set forth in Figure 1 (where the Tg's of the first layer and the third layer are the same) and with the original claims (where the Tg's of the various layers are all different). Claim 17 was newly added at this point and contained the same claim language.

In the following Office action dated July 2, 2003, the Examiner set forth a rejection to claims 15 and 17 on the basis of indefiniteness. The Examiner stated in this Office action that the claims were unclear by reciting the first layer as having a temperature Tg1, the second layer as having a temperature as Tg2 and the third layer as having a temperature as Tg1, with the Tg1 of the first layer and the third layer able to either be the same or different. The Examiner suggested at the top of page 3 of this Office action that the glass transition temperature of the third layer should be denoted as Tg3 since Tg1 would clearly denote the Tg of the first layer and since the respective temperatures can either be the same or different. The subsequent Office action response amended the claims in accordance with the Examiner's suggestion, such that the third layer's glass transition temperature was denoted as Tg3 with Tg1 of the first layer and Tg3 of the third layer being either the same or different.

As noted above, the Examiner argues that even if it is assumed that there is support for the glass temperatures of the first and third layers being either the same or different, there would not be support for the Tg3 being lower than Tg2 (Examiner's Answer, page 11, lines 4-8). The Applicant respectfully disagrees.

It is respectfully submitted that one skilled in the art upon reviewing the original specification would readily recognize that it is essential that the three-layered configuration, as shown in Figure 1 and described in the specification, has the Tg of the polymer of the center layer (matrix 2 having Tg2) be higher than the Tg of the polymers of each of the adjacent outer layers (matrix 1a, 1b – Tg1, Tg3, respectively). This is shown by virtue of Figure 1, as well as discussed on page 10, line 18 (...with  $Tg2 > Tg1$ ). Since one skilled in the art would recognize by way of a review of the specification and

Figure 1 that the glass transition temperatures of the first layer and the third layer (originally both represented by Tg1, but the latter currently represented by Tg3) could be the same or different, as explained above, it would logically follow that Tg2 would have to be greater than Tg1 (the Tg of the first and third layers) – regardless as to whether the glass transition temperatures of the first layer and the third layer are the same or different, and regardless as to whether the glass transition temperatures of the first and third layers are represented by Tg1, Tg3 or some other designation.

According to the present specification, and as disclosed in the original specification and claims, the layered construction of the therapeutic system comprises the features of two polymer-containing layers that are laminated upon each other, and whereby these adjacent layers differ with respect to their respective glass transition temperature (page 10, lines 1-5). This requirement must also be met when more than two polymer-containing layers are laminated together (as set forth in original claim 5). Hence, in each case of two adjacent layers, these layers must have different respective glass transition temperatures. This requirement is also met by the embodiment of Figure 1 where the Tg of the polymer of the upper layer 1a is different from the Tg of the polymer of the center layer (Tg2), and likewise the Tg of the polymer of the lower layer 1b is different from the Tg of the polymer of the center layer (Tg2).

In turn, when the general teaching of the present invention, as disclosed on page 10, lines 1-5 and in original claims 1 and 5, is applied to a three-layered system, this system would comprise an upper layer which is laminated onto a center layer, and a lower layer which is laminated to the opposite side of the center layer. In this case, the upper layer and the lower layer each contains polymers which differ in their glass

transition temperature from the polymers of the center layer to which each of these outer layers is laminated. However, the present invention does not contain any limitations for defining the relationship between the Tg of polymers which are present in layers which are not directly laminated (or adjacent) to each other. In particular, the present invention does not require the polymers of the upper or lower layer to have either an identical or different Tg, as long as the requirement is met which requires that those layers which are laminated upon one another contain polymers which differ in their glass transition temperature (specification, page 10, lines 1-5). The present invention does not include any limitations which refer to the relationship between the glass transition temperatures of polymers of non-adjacent layers (which are not laminated upon one another). Therefore, the Applicant respectfully submits that the Tgs of two non-adjacent layers may be identical or different, as set forth in the present claims and in accordance with the original specification.

It is respectfully noted that the present specification does not contain any explanation to provide a reason as to why these two outer layers (1a, 1b) should comprise polymers with an identical Tg, and there is no obvious technical effect that would be attributable to this limitation. As noted in the Appeal Brief, the only advantage that would be easily recognized to one skilled in the art is that such systems which have identical layers 1a, 1b (as shown in Figure 1) are easier and less expensive to manufacture. However, the skilled artisan would realize that this represents a preferred embodiment, but does not constitute an essential requirement according to the teaching of the present invention. It is respectfully submitted that this is akin to where the Examiner states in the Answer (page 18) that, in reference to Otsuka, et al., the feature of placing

the film or sheet next to the polymer layer is a *preferred* (emphasis provided) embodiment for the exemplified two-layer device and the term “preferred” does not denote criticality to this embodiment (Answer, page 18, lines 6-8).

In light of the aforementioned passages of the present specification, the Appellant respectfully submits that the specification provides sufficient support for a system having three layers, where the first layer has a polymer with Tg1, the second layer has a polymer with Tg2 and the third layer has a polymer with Tg3 and where Tg1 and Tg3 may be different (or identical) and where Tg2 is greater than Tg1 and Tg3. The limitation “or different” is clearly supported by the specification and is not new subject matter.

Withdrawal of this rejection is respectfully requested.

**Rejection of claims 33-43 under 35 U.S.C. 103(a)**

The Applicant again respectfully traverses the rejection of claims 33-43 as being unpatentable over U.S. Patent No. 5,151,271 (Otsuka, et al.) by itself or in view of U.S. Patent No. 6,063,838 (Patnode, et al.). The Applicant first submits that, contrary to the Examiner’s conclusion, Otsuka, et al. do not provide a clear teaching according to which it would be essential that the polymer of the polymer layer has a Tg that is higher than the Tg of the polymer of the macromolecular layer.

As explained in the response to the Final Office action, the Applicant respectfully submits that Otsuka, et al. teaches overlapping Tg ranges for the (drug-containing) polymer layer and the (adhesive) macromolecular substance layer (col. 2, lines 16-27; col. 3, lines 3-13). In the Examples of Otsuka, et al., the Tg of the drug-containing layer (polymer layer) is lower or higher than the Tg of the macromolecular substance layer (Example 3 vs. Examples 1 and 2). Therefore, the Applicant submits that Otsuka, et al.’s

teaching relating to the glass transition temperatures is restricted to two-layered embodiments. It is further submitted then that if Otsuka, et al. do not provide a clear teaching on glass transition temperatures in the layers of a two-layered preparation, the Tg of a third layer (which is not even taught or described by Otsuka, et al., as discussed below) is speculative and based on impermissible hindsight.

The Examiner states in the Answer (page 4) that Otsuka, et al. teaches a pressure sensitive adhering composite medicinal preparation to provide drug supply to the skin and that the composite comprises at least two layers, namely, at least one pressure-adhering macromolecular layer substance layer and polymer layer adjacent to the macromolecular substance layer (citing Abstract, and column 2, lines 1-10).

As noted on page 5 of the Examiner's Answer, the Examiner states that although Otsuka, et al. suggests more than two polymer layers, the reference does not exemplify the third layer. However, the Examiner maintains that it would have been obvious to one of ordinary skill in the art to look to the guidance of Otsuka, et al. and incorporate a third polymer containing layer. The motivation, according to the Examiner, would be since Otsuka, et al. teaches that the composite should contain *at least* (emphasis provided) two layers and in particular *at least one* (emphasis provided) macromolecular layer, thus suggesting the incorporation of more than one macromolecular layer.

With reference to Patnode, et al., the Examiner states that the reference teaches a blended pressure-sensitive adhesive which is formed from at least two polymeric materials with at least one being a pressure sensitive adhesive. The Examiner thus concludes that it would have been obvious to combine the teachings of Otsuka, et al. and



Patnode, et al. to utilize a third pressure sensitive layer in order to arrive at the presently claimed invention.

In response to the Appellant's arguments, the Examiner states in the Answer (page 13, lines 1-13) that the Appellant had criticized Otsuka's use of the phrase "at least two layers" as a "vague teaching" and that it is unclear if this is in fact a suggestion of more than two polymers and the Examiner notes the Appellant's own use of the same purportedly "vague teaching" on page 9 and 10 of the specification to derive support for the instant claims comprising more than two layers. The Examiner in essence states that the Appellant attempts to argue that this is a vague teaching and "at least two" does not mean more than two layers with regard to Otsuka, et al., whereas with regard to the instant specification, "at least two" is ample disclosure of more than two layers. The Appellant respectfully disagrees with the Examiner's interpretation of the previously filed arguments.

The Appellant had not criticized Otsuka, et al.'s use of the phrase "at least two layers" as being "vague and unclear." Moreover, the Appellant had not argued that "at least two layers" in regards to Otsuka, et al. does not mean more than two. The Appellant respectfully submits that Otsuka, et al. simply fails to teach more than one macromolecular layer and more than one polymer layer. Otsuka, et al. teaches "at least two layers" (col. 2, line 5). Of these "at least two layers," a layer (i.e., one layer) is a layer of a macro-molecular substance (col. 2, lines 5-6) and a layer (i.e., one layer) is a polymer layer adjacent to said macromolecular substance layer (col. 2, lines 7-9). The Examiner's interpretation of Otsuka, et al. is that the reference teaches "at least two layers, namely, at least one macromolecular layer and at least one polymer layer."

However, this is not what Otsuka, et al. teaches. The reference teaches, as clearly set forth throughout the reference, at least two layers, one of which is a macromolecular substance layer and one of which is a polymer layer.

In addition, it is respectfully submitted that the macromolecular layer of Otsuka, et al. serves to secure adhesion of the preparation to the skin (col. 3, lines 3-6) and so there would be no reason why the preparation of Otsuka, et al. should contain additional adhesive layers. Moreover, as previously noted by the Appellant, throughout the reference of Otsuka, et al. the terms “macromolecular layer” and “polymer layer” are referred to only in singular form. Had additional layers been contemplated, then it is respectfully submitted that such a disclosure (e.g., “at least one macromolecular layer, the macromolecular layers, the macromolecular layer(s), etc.) would have been set forth. Such disclosure is absent throughout Otsuka, et al. For example, column 4, lines 29-34 recite “Furthermore, for improvement in shape-holding property or adhesiveness or for controlled release of the drug, the above-mentioned macromolecular substance layer (*not layers*) and polymer layer (*not layers*) each may be crosslinked, for example, by using a chemical crosslinking agent or by irradiation with ultraviolet light or electron rays.”

As noted above, the Examiner states that the Appellant previously argued that “at least two” in Otsuka, et al. is vague and unclear and does not mean more than two layers. It is respectfully submitted that it appears the Examiner has misinterpreted what the Appellant previously argued, and so further explanation is provided herewith.

The Appellant respectfully submits that what is vague and unclear is not whether “at least two layers” in Otsuka, et al. means more than two, but rather whether the “at least two layers” would imply that the additional layers over two would be additional

macromolecular or polymer layers, as argued by the Examiner, or whether the phrase indicates whether the preparation may contain additional layers, such as films and sheets, as noted in claim 11 (see also the Examples). Moreover, the second paragraph of Otsuka, et al.'s claim 1 refers to "one of said layers (a) and (b)" and to "[the] other of said layers" (that is, layers (a) and (b))." This further shows that Otsuka, et al. considered only one macromolecular substance layer combined with only one polymer layer (see also, col. 6, lines 34-38 "from the layer ... to the other layer;" col. 6, line 7 "both the layers.")

On pages 13-14 of the Examiner's Answer, the Examiner states that the Appellant highlighted the portion of Otsuka, et al. as follows, which states:

"...a layer of a macromolecular substance having pressure-sensitive adhesiveness at ordinary temperatures and a polymer layer..."

but failed to highlight the portion wherein Otsuka, et al. teaches

"...a composition preparation characterized comprises at least two layers, namely, a layer of a macromolecular substance layer and ... a polymer layer adjacent to said macromolecular substance layer, that at least one of the macromolecular substance layer and polymer layer at least contains ... and the other at least contains..."

The Examiner cites this passage as clearly supporting that Otsuka, et al. can have more than one macromolecular layer.

As noted in the Appeal Brief, the Appellant respectfully disagrees with the Examiner's interpretation of Otsuka, et al. The passage states that (1) either the macromolecular substance layer or the polymer layer, or (2) the macromolecular substance layer and the polymer layer," at least contains a percutaneously absorbable drug and the other at least contains an adjuvant. In other words, "one of said layers (a) and (b) at least contains a ... drug and [the] other of said layers at least contains an adjuvant..."

The above recitation of Otsuka, et al. does not teach “at least one macromolecular layer,” as alleged by the Examiner.

As noted in the Appeal Brief, the Appellant respectfully submits that Otsuka, et al. teach as follows:

1. that there are at least two layers;
2. one of these layers is a macromolecular polymer layer;
3. another of these layers is a polymer layer;
4. the macromolecular layer and the polymer layer are adjacent to each other;
5. at least one of the macromolecular layer and the polymer layer (e.g., the macromolecular layer) at least contains a percutaneously absorbable drug;
6. the other layer (e.g., the polymer layer) at least contains an adjuvant capable of increasing percutaneous drug absorption;
7. the polymer layer is supported on one side (i.e., the side not adjacent to the macromolecular layer) by a film or sheet (which is another layer of the “at least two layers”); and
8. the macromolecular layer may preliminarily include formation on a release liner followed by transfer of the macromolecular layer onto the polymer layer for lamination.

The teaching of Otsuka, et al. clearly does not include “at least one macromolecular layer,” but rather just a single macromolecular layer.

With regard to the sandwich configuration of the presently claimed system, it was stated on page 5 of the Answer (lines 13-15) that Otsuka, et al. teach that the

macromolecular layer must be in contact and adjacent to the polymer layer. However, the cited passage (col. 2, lines 5-10) only generally teaches that the two layers must be in contact with each other so that the drug and adjuvant respectively can migrate into the adjacent other layer (col. 2, lines 13-15). This passage fails to teach anything about the relative position of a purported further macromolecular layer.

On pages 15-18 of the Answer, various possible configurations that may be derived from Otsuka, et al.'s disclosure are discussed. The Appellant respectfully submits that apart from the fact that Otsuka, et al. does not unambiguously teach the presence of a further macromolecular layer or polymer layer, as discussed above, it is further submitted that the various possible configurations are not easily derivable from the reference but rather are a result of impermissible hindsight analysis. Moreover, the conclusion drawn on page 15 of the Answer (last paragraph) appears to be speculative and there is no compelling reason why the configuration suggested by the Examiner would be "the only configuration that would work." According to Otsuka, et al., the function of the macromolecular layer is to provide pressure-sensitive adhesiveness to adhere the preparation to the skin (col. 3, lines 3-6). Adding a second adhesive layer to the opposite side of the polymer layer would not only be counterintuitive to the teaching of Otsuka, et al.

With regard to Otsuka, et al.'s inventive concept discussed on page 20 of the Examiner's Answer, it is respectfully submitted that the concept consists of keeping the drug and adjuvant in separate layers to prevent drug crystallization (col. 1, lines 47-55; col. 6, lines 22-26). However, following this concept does not necessarily lead one skilled in the art to the sandwiched construction defined by the present claims.

Referring now to Patnode, et al., the Examiner refers to the multilaminate device shown in Figure 15 in which a rate-controlling membrane is covered on both sides with a pressure sensitive adhesive layer. However, it should be pointed out that this membrane is not equivalent or comparable to the polymer layer taught by Otsuka, et al. According to Otsuka, et al., the (non-adhesive) polymer layer contains either a drug substance or an adjuvant (claim 1, paragraph 2), whereas the membrane taught by Patnode, et al. does not contain such substances. In this regard, the Examiner states that the polymer layer of Otsuka, et al. acts as a rate-controlling membrane. However, according to Otsuka, et al., the function of the polymer layer is to increase the extent of migration of drug and adjuvant (col. 2, lines 56-59), whereas the rate-controlling membrane mentioned by Patnode, et al. limits or restrains the flow of active substance. Therefore, even if it is assumed that Patnode, et al. suggested incorporating a second adhesive layer into the device of Otsuka, et al., there would be no suggestion provided regarding the sandwiched layer construction defined in present claim 1.

Patnode, et al.'s Figure 14 shows an embodiment having no membrane. In this case, both adhesive layers are adjacent and connected to each other. Likewise, Otsuka, et al. does not consider the possibility of incorporating a membrane. Therefore, where no membrane is present, Patnode, et al. teaches to arrange both adhesive layers adjacent to each other. With respect to Patnode, et al., it may also be pointed out that this reference teaches that each pressure-sensitive adhesive layer should contain a blend of at least two components, the first component being a pressure-sensitive adhesive, the second component being a fibrillous to schistose material (col. 2, lines 46-55). From this description, it appears that the polymers present in these two components differ with

respect to their glass transition temperature, and each pressure-adhesive layer, therefore, contains a mixture of polymers having different glass transition temperatures (one forming a continuous domain, the other forming a fibrillous domain). This, however, is not in accordance with the present invention, which provides that the polymers having different glass transition temperatures to be present in different layers (specification, page 8, lines 4-9).

In light of the aforementioned deficiencies of the combination of teachings of Otsuka, et al. and Patnode, et al., the Appellant again respectfully submits that the combination of references fails to teach every limitation set forth in claims 33-43 and that due to these deficiencies, one skilled in the art would not have been motivated to combine these references to arrive at the present invention. Withdrawal of this rejection is strongly requested.

In response to the second rejection under Section 103(a), the Appellant again respectfully traverses and disagrees for at least the numerous aforementioned deficiencies of Otsuka, et al. Moreover, the separating layer of Chien, et al.'s example 8 (Examiner's Answer – last paragraph) does not contain any drug substance or any adjuvant capable of increasing percutaneous drug absorption (Otsuka, et al., claim 1, paragraph 2). Therefore, this separating layer is not equivalent or comparable to the “polymer layer” taught by Otsuka, et al.

According to the Examiner (Answer, page 23, lines 1-5), the motivation to utilize two drug-containing layers is to provide combination therapy. However, Otsuka, et al. teaches only two layers which are potentially drug-containing (polymer layer, macromolecular substance layer; claim 1 & col. 6)). Therefore, when it is mentioned in

column 5, lines 51-52, that the drugs may be used in combination of two or more, it is respectfully submitted that one skilled in the art would understand that the combination of drugs is present within one of said layers (or each layer containing a different drug). Also, Example 8 of Chien, et al. concerns the particular case where an estrogen (ethinyl estradiol) is combined with a gestagen (norethindrone). However, such hormones are not considered by Otsuka, et al. (col. 5, lines 14-50).

In light of the deficiencies of the combination of the teachings of Otsuka, et al. and Chien, et al., the Appellant respectfully submits that the combination of references fails to teach every limitation set forth in present claims 33-43 and that due to these deficiencies, one skilled in the art would not have been motivated to combine these references to arrive at the present invention.

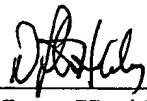
### **SUMMARY**

The Appellant respectfully submits that the cited references do not teach, suggest or show the present invention as presently claimed or advantages attendant thereto. In conclusion it is requested that the rejection of claims 33-43 as failing to comply with the written description requirement, as being unpatentable over U.S. Patent No. 5,151,271 (Otsuka *et al.*) in view of U.S. Patent No. 6,063,838 (Patnode, *et al.*) under 35 U.S.C. §103(a) and as being unpatentable over U.S. Patent No. 5,151,271 (Otsuka *et al.*) in view of U.S. Patent No. 5,023,084 (Chien, *et al.*) under 35 U.S.C. §103(a) be withdrawn, that the Board reverse the decision of the Examiner and allow claims 33-43.



Respectfully submitted,

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